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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,985	11/03/2000	Dirk M. Anderson	2874-US-CNT	6890

22932 7590 05/03/2007  
IMMUNEX CORPORATION  
LAW DEPARTMENT  
1201 AMGEN COURT WEST  
SEATTLE, WA 98119

EXAMINER
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STANDLEY, STEVEN H

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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05/03/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

09/705,985

Applicant(s)

ANDERSON ET AL.

Examiner

Steven H. Standley

Art Unit

1649

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 9, 11, 13, 15-18, 20, 21, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 17 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5, 9, 11, 13, 15-16, 18, 20, and 25-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Detailed Action***

1. The finality of the rejection of the last Office action is withdrawn. The examiner, while rejecting claims 5, 9, 11, 13, and 15 under 35 USC 112, 1<sup>st</sup> paragraph, written description, failed to correctly reject claims 16, 18 and 20 as well. Those claims are herein rejected under the same statute. Furthermore, the examiner finds no basis for claims to 90% of a ***fragment*** of RANK. A new matter rejection is therefore also made by the examiner below.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Rejection of claim 5, 9, 11, 13, and 15-16, 18, and 20 under 35 USC § 112, 1<sup>st</sup> paragraph, written description is maintained for the reasons made of record in the office action dated 11/17/05 and 7/28/06. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues that the specification and claims satisfy the written description. Applicant is referred to pages 2-3 of the prior office action in which the stringency was described as encompassing variants with 63-65 percent identity based on a 1% mismatch conferring a 1 degree drop in T<sub>m</sub> (see appendix A from the last action). SEQ ID NO: 1 of the instant application is about 3100 base pairs and has a T<sub>m</sub> at 99 degrees. More than a thousand base pairs of SEQ ID NO: 1 are non-coding. Therefore, if all the variation, or mismatch, in the DNA sequence

Art Unit: 1649

of SEQ ID NO: 1 resides in the coding region, the resulting polypeptides encompassed by the conditions recited would be far more than merely 63-65 percent variation estimated for the DNA variants encompassed as well. As argued in the previous office action, applicant does not have written description for variants encompassing such low DNA (and polypeptide) sequence identity. Furthermore, a recitation of 90% in the claim does not have adequate written description in the specification. Applicant has not defined any structural features of the instant polypeptide as they relate to its function of binding RANKL. The skilled artisan cannot envision the detailed changes encompassed by the genus claimed that function as recited by the claims.

Applicant states that the specification teaches that soluble forms of RANK are the ones that bind RANKL and that the sequence specified (33-213) is the soluble form. However, applicant is claiming 90% identity to that sequence and the specification describes no variants of that sequence that bind RANKL with any percent identity.

3. Claims 5, 9, 11, 13, and 15-16, 18, 20, and 25-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification discloses variants of 90% identity to SEQ ID NO: 2 (which contains 616 amino acids total), but there is no basis in the specification for claiming 90% variants of the FRAGMENT of amino acids 33-213 of SEQ ID NO: 2.

Art Unit: 1649

### **Conclusion**

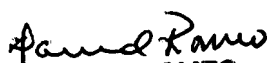
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.  
4/18/07



  
**DAVID S. ROMEO**  
**PRIMARY EXAMINER**